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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

LANDSMAN, ROBERT S

ART UNIT PAPER NUMBER

1647

DATE MAILED: 03/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/499,468

Applicant(s)

ALDERSON ET AL.

Examiner

Robert Landsman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 November 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 42-71 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 42-71 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 15, 16.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: Sequence Comparison

DETAILED ACTION

1. Formal Matters

- A. The Information Disclosure Statement, filed 11/29/01, has been entered into the record.
- B. The Information Disclosure Statement, filed 12/20/01, has been entered into the record.
- C. The Information Disclosure Statement, filed 12/21/01, has been entered into the record.
- D. Claims 1-41 were pending in the application and were subject to restriction. In Amendment B, filed 11/29/01, Applicants elected Group I, claims 1-11 and 15-17, with traverse. Applicants argue that it would not be a serious burden to search Groups I-VIII. However, in Amendment B, Applicants canceled all pending claims and added new claims 42-71, which all fall into elected Group I. Therefore, claims 42-71 are pending and are the subject of this Office Action.

2. Information Disclosure Statement

- A. The Statutory Declarations cited on the IDS filed 12/21/01, have been considered, but they will not be listed on the face of any patent issuing from the application being examined.
- B. References BI-BN on the IDS filed 11/29/01 have been lined through since U.S. Patent Applications are not proper subject matter for an IDS.
- C. Reference DV on the IDS filed 11/29/01 has been lined through since there is no publication date, chapter number, editors, or press information in this citation.
- D. References FS and FT on the IDS filed 11/29/01 have been lined through since International Search Reports are not proper subject matter for an IDS.

3. Drawing Changes

- A. In Preliminary Amendment A, filed 2/27/01, Applicants requested approval of a drawing change. However, this change could not be found. A Draftsman's review of all drawings; however, is included in this Office Action.

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4. Title

A. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The title is drawn to VEGF-2 whereas the claims are drawn to methods of using VEGF-2, or fragments thereof, to proliferate photoreceptor cells.

5. Claim Rejections - 35 USC § 101 - Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

A. Claims 42-71 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over at least claims 61-186 of U.S. Patent No. 5,932,540. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the patent and application is claiming common subject matter, as follows: the present claims are drawn, generally, to a method of proliferating photoreceptor cells in a patient by administering a polypeptide comprising SEQ ID NO:2, or a fragment thereof. The application also claims the use of polyethylene glycol and the use of various routes of administration for pharmaceutical compositions comprising various doses of SEQ ID NO:2. Claims 61-186 of the patent recite, generally, method of stimulating proliferation of endothelial cells in a patient comprising administering to the patient the polypeptide of SEQ ID NO:2, wherein the patient has a wound. The patent also teaches the use of polyethylene glycol and pharmaceutical compositions of varying amounts and routes of administration.

The polypeptides of both the application and patent are identical and the protein of the patent comprises residues of claims 42, 52 and 62 of the application, as recited in the application. Therefore, the artisan, in practicing the method of the patent by administering the protein of SEQ ID NO:2, would inherently be practicing the method of the application. In other words, in administering the protein of SEQ ID NO:2 to stimulate endothelial cell proliferation, the artisan would inherently be proliferating

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photoreceptors since they are administering identical compounds. Therefore, although the conflicting claims are not identical, they are not patentably distinct from each other because the process steps of administering VEGF-2, or a fragment thereof, is the same regardless of whether the purpose is to stimulate endothelial cell proliferation or proliferate photoreceptors (Ex parte Novitski, 26 USPQ 1391). VEGF-2 would inherently possess photoreceptor stimulating activity.

B. Claims 42-71 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over one or more of claims 62-150 of U.S. Application No. 09/107,997. This application was not available to the Examiner at the time this Office Action was written. However, it is known that this application contains claims drawn to methods of using the protein comprising, in whole or in part, SEQ ID NO:2. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are claiming common subject matter, as follows: the claims of the application are seen above. Claims 62-150 of '997 recite, generally, method of administering VEGF-2, or a fragment thereof, to a patient. The '997 application also teaches the use of polyethylene glycol and pharmaceutical compositions of varying amounts and routes of administration.

The polypeptides of both applications are identical and the protein of '997 comprises residues of claims 42, 52 and 62 of the application, as recited in the application. Therefore, the artisan, in practicing the method of '997 by administering the protein of SEQ ID NO:2, would inherently be practicing the method of the present application. In other words, in administering the protein of SEQ ID NO:2 of '997 to a patient, the artisan would inherently be proliferating photoreceptors since they are administering identical compounds. Therefore, although the conflicting claims are not identical, they are not patentably distinct from each other because the process steps of administering VEGF-2, or a fragment thereof, is the same regardless of whether the purpose is to proliferate photoreceptors, or for some other purpose (Ex parte Novitski, 26 USPQ 1391). VEGF-2 would inherently possess photoreceptor stimulating activity.

C. Claims 42-71 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over at least claims 22 and 27 of U.S. Application No. 10/084,488. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are claiming common subject matter, as follows: the claims of the application are seen above. Claims 22 and 27 of '488 recite, generally, method of treating a patient by administering VEGF-2, or a fragment thereof. The '488 application also teaches the use of polyethylene glycol and pharmaceutical compositions of varying amounts and routes of administration.

The polypeptides of both applications are identical and the protein of '488 comprises residues of claims 42, 52 and 62 of the application, as recited in the application. Therefore, the artisan, in practicing the method of '488 by administering the protein of SEQ ID NO:2, would inherently be practicing the method of the present application. In other words, in administering the protein of SEQ ID NO:2 of '488 to a patient, the artisan would inherently be proliferating photoreceptors since they are administering identical compounds. Therefore, although the conflicting claims are not identical, they are not patentably distinct from each other because the process steps of administering VEGF-2, or a fragment thereof, is the same regardless of whether the purpose is to proliferate photoreceptors, or for some other purpose (Ex parte Novitski, 26 USPQ 1391). VEGF-2 would inherently possess photoreceptor stimulating activity.

D. Claims 42-71 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over at least claim 86 of U.S. Application No. 10/127,551. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the patent and application is claiming common subject matter as discussed in rejections A-C above (Ex parte Novitski, 26 USPQ 1391).

E. The Examiner brings to Applicants' attention that claims 42-71 may be provisionally rejected under the judicially created doctrine of double patenting over one or more claims of copending Application No. 10/120,398 and, 10/060,523. Upon performing a search of claimed SEQ ID NO:2 of the present application, Applications 10/120,398 and 10/060,523 were identified as containing a sequence which is 100% identical to this sequence. However, these applications were not available to the Examiner at the time this Office Action was written. Applicants are hereby informed that a provisional double patenting rejection may be made in a subsequent Office Action.

6. Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

A. Claims 42-71 are rejected under 35 U.S.C. 102(e) as being anticipated by Hu et al. (U.S. Patent No. 5,932,540). The teachings of both the present application and the patent are recited in paragraph A of the above double-patenting rejection. The process steps of administering VEGF-2, or a fragment thereof, is the same regardless of whether the purpose is to stimulate endothelial cell proliferation or proliferate photoreceptors (Ex parte Novitski, 26 USPQ 1391). VEGF-2 would inherently possess photoreceptor stimulating activity.

B. Claims 42-49, 52-59, 62-69 are rejected under 35 U.S.C. 102(e) as being anticipated by Alitalo et al. (U.S. Patent No. 6,130,071). Alitalo et al. teach a protein which is 99.6% identical to SEQ ID NO:2 of the present invention (Sequence Comparison A). Alitalo et al. also teach pharmaceutical compositions, including, oral, topical, parenteral, as well as sustained-release formulations (column 14, line 53 to column 15, line 7) and a water-soluble polymer, including polyethylene glycol (column 6, lines 26-33). Although the conflicting claims are not identical, they are not patentably distinct from each other because the process steps of administering VEGF to a patient are the same regardless of the purpose (Ex parte Novitski, 26 USPQ 1391).

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7. Claim Rejections - 35 USC § 102/103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

A. Claims 50, 51, 60, 61, 70 and 71 are rejected under either 35 USC 102(e) or 35 U.S.C. 103(a) as being unpatentable over Alitalo et al. The claims recite administering VEGF-2 at doses of approximately 0.005 mg/kg – 50 mg/kg. Alitalo et al do not specifically teach administering the protein at this dosing range. However, it would have been obvious to one of ordinary skill in the art at the time of the present invention to have determined a range of dosages to administer to a patient. The present claims cover a 10,000-fold dosing range (0.005 – 50 mg/kg). In absence of evidence to the contrary, the dose of VEGF used in the Alitalo et al. would likely fall within this 10,000-fold range, especially in view of the 10-1000 pM concentration range for which VEGF is known to be effective (column 15, lines 35-40). Therefore, depending on the weight of the patient to be treated, 10-1000 pM may inherently fall in the 0.005 – 50 mg/kg range of the present invention.

8. Conclusion

A. No claim is allowable.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
March 06, 2003

